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APPLICATION NO.	FII	LING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,887	0	07/10/2003	Hayim Lindenbaum	U 014713-7 1672  EXAMINER	
140	7590	08/24/2005			
LADAS & 26 WEST 6		FT	VRETTAKOS, PETER J		
NEW YORI		023		ART UNIT	PAPER NUMBER
	·			3739	

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

			The				
	Application No.	Applicant(s)	1,000				
	10/616,887	LINDENBAUM ET	LINDENBAUM ET AL.				
Office Action Summary	Examiner	Art Unit					
	Peter J. Vrettakos	3739					
The MAILING DATE of this communication Period for Reply	appears on the cover sheet w	ith the correspondence add	lress				
A SHORTENED STATUTORY PERIOD FOR RE THE MAILING DATE OF THIS COMMUNICATIO  - Extensions of time may be available under the provisions of 37 CFI after SIX (6) MONTHS from the mailing date of this communication  - If the period for reply specified above is less than thirty (30) days, a  - If NO period for reply is specified above, the maximum statutory pe  - Failure to reply within the set or extended period for reply will, by st Any reply received by the Office later than three months after the m earned patent term adjustment. See 37 CFR 1.704(b).	ON. R 1.136(a). In no event, however, may a b. a reply within the statutory minimum of thin a riod will apply and will expire SIX (6) MOI tatute, cause the application to become A	reply be timely filed  ty (30) days will be considered timely.  NTHS from the mailing date of this cor  BANDONED (35 U.S.C. § 133).	mmunication.				
Status							
1) Responsive to communication(s) filed on 2	<u>8 July 2005</u> .						
- /	This action is non-final.						
3) Since this application is in condition for all			merits is				
closed in accordance with the practice und	er Ex parte Quayle, 1935 C.	D. 11, 453 O.G. 213.					
Disposition of Claims							
4) Claim(s) 11-20 is/are pending in the applic	ation.						
4a) Of the above claim(s) is/are with	4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.							
6)⊠ Claim(s) <u>11-20</u> is/are rejected.							
•	') Claim(s) is/are objected to.  Claim(s) are subject to restriction and/or election requirement.						
o)[ Claim(s) are subject to restriction at	id/of election requirement.						
Application Papers							
9) The specification is objected to by the Exar		= .					
	10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the co			:R 1 121(d)				
11) The oath or declaration is objected to by th							
·—							
Priority under 35 U.S.C. § 119	ata a a da ata a a a a a a a a a a a	C 440(a) (d) a= (6)					
<ul><li>12) Acknowledgment is made of a claim for for</li><li>a) All b) Some * c) None of:</li></ul>	eign phonty under 35 U.S.C.	9 119(a)-(u) or (i).					
1. Certified copies of the priority docum	nents have been received.						
2. Certified copies of the priority docum		Application No					
3. Copies of the certified copies of the priority documents have been received in this National Stage							
application from the International Bu	- · · · · · · · · · · · · · · · · · · ·						
* See the attached detailed Office action for a	list of the certified copies no	t received.					

U.S. Patent and Trademark Office

PTOL-326 (Rev. 1-04)

1) Notice of References Cited (PTO-892)

Paper No(s)/Mail Date 8/3,1/5,2/5.

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)

Attachment(s)

4) Interview Summary (PTO-413)

6) Other: \_

Paper No(s)/Mail Date. \_\_\_

5) Notice of Informal Patent Application (PTO-152)

#### **DETAILED ACTION**

Claims 11-20 are elected without traverse 7-28-05. Claims 1-10 are non-elected.

### Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is rejected as failing to define the invention in the manner required by 35 U.S.C. 112, second paragraph.

The claim(s) are narrative in form and replete with indefinite and functional or operational language. The structure which goes to make up the device must be clearly and positively specified. The claim neglects to positively identify new structure. (Instead the claim is a characterization of the device's placement during use as depicted in Applicant's figure 2).

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application

Art Unit: 3739

by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 11-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Dubrul et al. (6,450,989).

Dubrul discloses a hemostasis device (col. 10:54-60; see figure 2) with an anchor balloon (4), a peripheral balloon (9), electrodes (col. 18:5-18), and a radiation (analogous but not necessarily anticipatory here to RF) power source (patented claim 5).

Note: claim language regarding the effects of the electrodes (heating blood volume, coagulating blood, and closing a puncture) are toward the intended use of the device and carry no patentable weight in a device claim. In other words, sufficient anticipation is shown by the disclosure of electrodes in the prior art.

#### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3739

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 13 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dubrul in view of Kontos (5,928,266).

Dubrul refers RF energy in col. 1:52-56.

Dubrul neglects to expressly disclose blood volume delimiting. Kontos discloses a hemostasis device (analogous to Dubrul) comprising a pair of electrodes (304, figure 17, also see patented claims 1 and 3), and an RF generator (col. 6:50). Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Dubrul in view of Kontos by using Dubrul for hemostasis in a manner analogous to that in Kontos figure 9 (sealing material 78 would merely be substituted by the peripheral balloon (9) in Dubrul). The motivation to use Dubrul in this manner would be to simply choose a well-known method of hemostasis for the disclosed Dubrul device.

Note: delimiting blood volume is borderline intended use language. This was addressed in the 112 rejection above. However, because Dubrul only makes reference to hemostasis (col. 10:54-60) once, Kontos is presented, which depicts in figure 9 a hemostasis device with an anchor balloon (20) and sealing material (78 – analogous to a "peripheral" balloon). Further, Kontos depicts a pair of electrodes (304, figure 17), whereas Dubrul refers to "electrodes" (col. 18:5-18), but does not refer to multiple electrodes on a single embodiment. (The Dubrul disclosure of "electrodes" instead is only with reference to multiple speculated embodiments).

Art Unit: 3739

Claims 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dubrul in view of Kontos and further in view of Woltosz (4,211,230).

Dubrul and Kontos neglect to disclose feedback control during hemostasis.

Woltosz discloses an electrosurgical device (generic term) and a corresponding hemostatic method including radiofrequency electrodes, feedback control, and parameters making obvious the Applicant's claims. Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Dubrul in view of Kontos and further in view of Woltosz by integrating the Woltosz feedback controller as well as disclosed parameters, into the Dubrul/Kontos device and method, respectively. The motivation to use Woltosz in this manner would be to simply choose a well-known design expedient and hemostasis parameters for the speculated Dubrul/Kontos device.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3739

Page 6

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pete Vrettakos August 5, 2005

ROY D. GIBSON PRIMARY EXAMINER